

March 27, 2009

NOTICE

Our file number: 09-108446-55

To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada

Electronic smoking products (i.e., electronic products for the vaporization and administration of inhaled doses of nicotine including electronic cigarettes, cigars, cigarillos and pipes, as well as cartridges of nicotine solutions and related products) fall within the scope of the *Food and Drugs Act*. All of these products require market authorization prior to being imported, advertised or sold in Canada. Market authorization is granted by Health Canada following successful review of scientific evidence demonstrating safety, quality and efficacy with respect to the intended purpose of the health product. This evidence is provided by the sponsor seeking market authorization. To date, no electronic smoking product has been authorized for sale by Health Canada.

In the absence of evidence provided by the sponsor establishing otherwise, an electronic smoking product delivering nicotine is regulated as a New Drug under Division 8, Part C of the *Food and Drug Regulations*. In addition, the delivery system within an electronic smoking kit that contains nicotine must meet the requirements of the *Medical Devices Regulations*. Appropriate establishment licences issued by Health Canada are also needed prior to importing, and manufacturing electronic cigarettes.

Health Canada is aware that some electronic smoking products have been advertised and sold in Canada without market authorization from Health Canada. Persons who may be importing, advertising or selling electronic smoking products without the appropriate authorizations are asked to stop doing so immediately. Products that are found to pose a risk to health and/or are in violation of the *Food and Drugs Act* and related *Regulations* may be subject to compliance and enforcement actions in accordance with the Health Products and Food Branch Inspectorate's Compliance and Enforcement Policy (POL-0001).

If you wish to submit a complaint about the advertising or sale of a health product without market authorization, please contact the Health Products and Food Branch Inspectorate.

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The following Web links are provided for your information:

"How to Submit a Trade Complaint":

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php

For information pertaining to applications and submissions for drugs and health products:

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index-eng.php>

Information about establishment licensing requirements may be found at:

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index-eng.php>

Sponsors interested in seeking market authorisation for electronic smoking products may contact Health Canada's Therapeutic Products Directorate for information about the drug submission process at: SIPDMail@hc-sc.gc.ca.